

## **REMARKS**

### ***Status of the Claims***

The present Office Action addresses and rejects claims 1-9 and 13-27.

### ***Rejection Pursuant to 35 U.S.C. §103***

#### **Claims 1-4, 6, 7, 9, 13-15, and 17-26**

The Examiner rejects claims 1-4, 6, 7, 9, 13-15, and 17-26 pursuant to 35 U.S.C. §103(a) as being obvious over US 2003/0032915 A1 to Saul (“Saul 915”) in view of U.S. Patent 6,533,733 to Ericson et al. (“Ericson”). Applicant respectfully disagrees.

In relevant part, independent claim 1 recites providing an implantable shunt system having an adjustable resistance valve for regulating the flow of cerebrospinal fluid (CSF) into and out of a ventricular cavity and a selectively operable external system controller device for communicating remotely via telemetry with the implantable shunt system, and manually reenergizing the implantable shunt system with the system controller device. Similarly, in relevant part, independent claim 17 recites an implantable shunt system having an adjustable resistance valve for regulating the flow of CSF into and out of a ventricular cavity and a system controller device for communicating remotely via telemetry with the implantable shunt system and configured to manually energize the implantable shunt system.

The Examiner relies on Saul 915 to teach the claimed invention but admits that Saul 915 fails to teach that an external system controller communicates with the shunt and valve system via remote telemetry. The Examiner thus relies on Ericson for this feature, arguing on page 3 of the Office Action that “it would have been obvious to one having ordinary skill in the art at the time of invention to add an external controller that communicates via telemetry as disclosed by Ericson to the cerebrospinal shunt system taught by Saul [915] in order to enable remote monitoring and control, as taught by Ericson.” However, as discussed further below, Saul 915 and Ericson do not teach or suggest the claimed invention to a person of ordinary skill in the art at least because combining Saul 915 and Ericson would require a substantial redesign of Saul 915, change the

principle of operation of Saul 915, and render Saul 915 inoperable for its intended purpose and because providing a manual means to replace an automatic activity is not inherently obvious.

Applicant's remarks below are preceded by quotations of related comments of the Examiner in single-spaced, small type.

The Examiner states on page 6 of the Office Action:

5. Applicant argues that one of ordinary skill in the art would not have been motivated to combine the Saul '915 reference with the Ericson reference, since the method and apparatus disclosed by Saul continuously monitors intracranial pressure and adjusts the valve accordingly, while Ericson discloses an external controller that is selectively operable to control the shunting system. Examiner respectfully disagrees. Taken together, the references reasonably suggest the apparatus and method claimed by applicant. All the steps and elements of the claimed method and apparatus are known in the art. One of ordinary skill in the art could have combined the claimed elements by known methods to yield the predictable result of a CSF shunt system that uses a remote monitoring system to adjust valve resistance based on ventricular pressure measurements, as suggested by the prior art. Accordingly, it is the position of the Examiner that the instantly claimed invention is not patentable over the cited prior art.

A *prima facie* case of obviousness cannot be established by merely pointing out the existence of particular claim elements in the prior art. MPEP §2143 and the Supreme Court's recent decision in *KSR Int'l Corp. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) underscore the deficiencies in the Office Action and the error of its obviousness rejection. The Supreme Court said that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 127 S. Ct. at 1741. The Examiner states that it would be obvious for one having ordinary skill in the art to combine elements of Saul 915 and Ericson but does not provide any analysis why that is true.

To make a *prima facie* showing of obviousness of a claimed invention, the Examiner should "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.*; see MPEP §2143.01(IV). Where no such explanation is given, as is the case here, improper use of hindsight can be inferred. Here, the Office Action makes conclusory statements suggesting use of the remote monitoring of Ericson with the adjustable shunt system of Saul 915 with no reason to do so aside

from adjusting valve resistance, which is already performed in the implanted system of Saul 915. Such rationale should be explicitly made under *KSR*. *See* MPEP §2141.

It is only with the benefit of Applicant's disclosure that the Examiner is able to choose the remote monitoring of Ericson and suggest combining it with Saul 915. That the Examiner, after having read Applicant's disclosure, can look at Saul 915, which the Examiner admits does not disclose remote telemetry, and choose to use the external controller of Ericson with Saul 915 does not bar patentability. Indeed, in light of Ericson's remote shunt system control requiring substantial redesign of Saul 915, changing the principle of Saul 915, and destroying the purpose of Saul 915 as discussed further below, it would not be obvious for one of ordinary skill in the art to combine Saul 915 and Ericson.

The Examiner states on page 7 of the Office Action:

6. Applicant further argues that using a manual energizing step in Saul would require a substantial redesign of the Saul device. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *See In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, the prior art teaches the steps of monitoring and controlling the valve based on measured fluid pressure that may be performed continuously as disclosed by Saul or upon the performance of an energizing step as disclosed by Ericson. As such, it is the position of the Examiner that, taken as a whole, the references reasonably suggest the claimed method and apparatus to one of ordinary skill in the art.

It appears that the Examiner is not addressing the Applicant's argument so as to develop a clear issue between the Examiner and Applicant. *See* MPEP §706.07. A *prima facie* case of obviousness is not established if the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." MPEP §2143.01(VI) quoting *In re Ratti*, 270 F.2d 810, 813, 123 USPQ 349, 352 (CCPA 1959). The Examiner has not made any argument refuting Applicant's position that substantial reconstruction and redesign of Saul 915 is required by combining Ericson with Saul 915, nor any argument refuting Applicant's position that such a combination changes the basic principle of Saul 915's operation. Accordingly, the Examiner has not established a *prima facie* case of obviousness.

Applicant again emphasizes that modifying Saul 915 to include the intervening step of manually energizing would require a substantial redesign and reconstruction of the device. Modifying Saul 915 to facilitate manual energization would require removing the existing internal controller and providing Saul 915 with a selectively operable external system controller device that is configured to manually energize the system. Saul 915's entire design relies on an implantable shunt and an implantable shunt control system. *See, e.g.*, FIG. 3; ¶ [0011]. All Saul 915's disclosed systems and methods for treating elevated intracranial pressure involve a self-contained system implanted in a patient that does not require any external intervention (except for necessities such as initial implantation and attention to post-implantation malfunctions). Accordingly, modifying Saul 915 with Ericson amounts to a substantial reconstruction and redesign of the Saul 915 device.

Even under the Examiner's purported test for obviousness, obviousness is not established because the combined teachings of Saul 915 and Ericson do not suggest the claimed invention to those of ordinary skill in the art. At the very least, as discussed above, the existence of various elements in the prior art is insufficient in itself to establish obviousness. Thus, even if as the Examiner asserts Saul 915 teaches the steps of monitoring and controlling the valve based on measured fluid pressure that may be performed continuously, and even if Ericson teaches the energizing step, the Examiner provides no, and there is no, reason or motivation for a person skilled in the art to combine the two references to reach the claimed invention.

Moreover, the Examiner appears to be mischaracterizing the test for obviousness and its accordant analysis. The portion of *In re Keller* cited by the Examiner is discussed in MPEP §2145(III). MPEP §2145(III) begins with *Keller* as stated by the Examiner, but the Examiner neglects the subsequent portion of the test directly following the quoted text of *Keller*: "However, the claimed combination cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose. See MPEP § 2143.01." Combining Ericson with Saul 915 changes *both* the principle of operation of Saul 915 and renders Saul 915 inoperable for its intended purpose, so their combination is improper and does not bar patentability of the claims.

First, combining the remote control of Ericson with Saul 915 as suggested by the Examiner changes Saul 915's principle of operation – i.e., *continuous and automatic* monitoring of a patient's

intracranial pressure using an *implanted* control system. Saul 915 is directed to an implantable valve system that includes an implantable control structure. The Examiner agrees, as indicated by the Examiner's reliance on a secondary reference for an external, non-implanted controller. Changing Saul 915 to have external components in its control system independently indicates a change in principle of operation. Furthermore, Saul 915's control system is directed to "continuously or at least frequently" monitoring a patient's intracranial pressure so frequent, automatic adjustments to the implanted valve can be made based on a patient's pressure level. ¶ [0010]; *see, e.g.*, [0011]-[0012]. Indeed, Saul 915 states that its controller *will* have such functionality. *See, e.g.*, ¶ [0033]. The focus of Saul 915's entire disclosed system is on transient pressure fluctuations not traditionally addressed by shunt systems, such as pressure changes resulting from changes in the patient's physical position that can happen often and at any time. *See, e.g.*, ¶ [0006] and [0031]. Thus, removing Saul 915's implanted controller and replacing it with the remote controller of Ericson not only changes but removes Saul 915's principle of operation because the control structure could not monitor and control transient pressure changes as principally designed.

Second, combining the remote control of Ericson with Saul 915 as suggested by the Examiner renders Saul 915 inoperable for its intended purpose. MPEP §2143.01(V) states that "[i]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." In the instant case, the purpose of Saul 915 is not just made unsatisfactory by modifying it with Ericson, Saul 915's purpose is eliminated. While Saul 915 may still be operable to monitor and control a shunt valve if combined with Ericson, the intended purpose of Saul 915 is not mere monitoring and control of a shunt valve. As previously discussed by Applicant, Saul 915's intended purpose requires *continuously monitoring* a patient's intracranial pressure and *automatically* opening or closing a valve in order to maintain a target pressure in the ventricles over a period of time. Thus, the modification of Saul 915 with Ericson as proposed by the Examiner makes Saul 915 unsuitable for its intended purpose. Simply put, no person having ordinary skill in the art would be motivated to modify a method and device aimed at continuous, automatic operation to include the intervening step of manually energizing.

The Examiner states on pages 7-8 of the Office Action:

7. Applicant argues that the step of manually energizing the apparatus distinguishes from the prior art, especially since the Saul device is preprogrammed and requires no manual intervention. The Examiner respectfully disagrees. It has been held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. See MPEP 2144.04(III). In the instant case, applicant claims a manual means that accomplishes the same result as a previously disclosed automatic activity. While the courts have not specifically held that such a conversion from automatic to manual activity is obvious, the court seems to suggest that merely moving between an automated and manual activity suggested in the prior art fails to provide a patentably distinct invention. Accordingly, it is the position of the Examiner that applicant's claims drawn to the manual steps of energizing, detecting, comparing, determining, and adjusting are unpatentable over the combination of Saul and Ericson which suggest the automatic performance of the steps claimed by applicant.

8. Applicant argues that replacing an automatic means with a manual means would result in a system that is inferior to the original, rendering the modification inherently nonobvious. The Examiner respectfully disagrees. As evidenced by Applicant's own disclosure, a manual process may not necessarily comprise an inferior process. Manual processes may, in fact, have advantages that are not found in an automatic process (for example, a manual automobile transmission often gets better gas mileage than an automatic transmission). Manual processes are not necessarily inferior, and the Examiner maintains that the recitation of a manual process to replace an automatic one does not render the instantly claimed method or apparatus patentable over the cited prior art.

While Applicant continues to respectfully disagree with the Examiner that moving from an automatic activity to a manual activity is inherently obvious, the Examiner's analysis still does not make claims 1 and 17 obvious. As discussed in MPEP 2144.04(III) and stated by the Examiner, "providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art." Combining Ericson with Saul 915 as suggested by the Examiner such that manual means perform an automatic activity does not *accomplish the same result*. As discussed above, the control system of Saul 915 is continuous and allows for monitoring and control of transient pressure changes. Replacing Saul 915's implanted, automatic, and continuous control system with the remote, manual control system of Ericson does not accomplish the same result as that offered by Saul 915 and thus does not bar patentability of claims 1 and 17.

Accordingly, for at least these reasons, it would not be obvious for a person skilled in the art to combine Saul 915 and Ericson, so independent claims 1 and 17, as well as claims 2-16 and 18-27

which depend directly or indirectly therefrom, distinguish over Saul 915 and Ericson, taken alone or combined, and represent allowable subject matter.

Claims 5, 8, 16, and 27

The Examiner rejects claims 5, 8, 16, and 27 pursuant to 35 U.S.C. §103(a) as being obvious over Ericson in view of Saul 915 and further in view of US 2003/0004495 A1 of Saul (“Saul 495”). The Examiner asserts that Ericson and Saul 915 teach the claimed invention “with the exception of repeating the resistance adjustment procedure at proscribed time intervals” and “a timed shut-off mechanism,” relying on Saul 495 to teach these features. Claims 5, 8, and 16 depend from independent claim 1, and claim 27 depends from independent claim 17. As discussed above, one skilled in the art would have no motivation to combine Ericson and Saul 915, and therefore claims 5, 8, 16, and 27 are allowable at least because they depend from allowable claims 1 and 17.

***Conclusion***

In view of the above remarks, Applicant submits that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Dated: August 4, 2008

Respectfully submitted,

By: /Christina M. Sperry/  
Christina M. Sperry  
Registration No.: 47,106  
NUTTER MCCLENNEN & FISH LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, Massachusetts 02210-2604  
(617) 439-2394  
(617) 310-9394 (Fax)  
Attorney for Applicant